

K060136

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PLANAR

JAN 31 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

<u>Summary Date:</u>	8 December 2005
<u>21 CFR 807.92(a)(1)</u> <u>Submitter's Information:</u>	Mr. Craig Harshman Planar Systems, Inc. 1195 NW Compton Drive Beaverton, OR 97006-1992 (503) 748-4661 (Phone) (781) 895-1133 (fax) craig_harshman@planar.com (Email)
<u>21 CFR 807.92(a)(2)</u> <u>Device Trade Name</u>	PLANAR DOME EX SERIES DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model E4c Color™
<u>Device common Name:</u>	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
<u>Device Classification Name:</u>	892.2050 Picture archiving and communications system
<u>Classification Product Code</u>	LLZ
<u>Establishment Registration Number:</u>	1226517
<u>Device Class:</u>	Class II
<u>Classification Advisory Committee:</u>	Radiology
<u>21 CFR 807.92(a)(3)</u> <u>Predicate Devices:</u>	The predicate devices: 510(k) Number: K013922 Decision Date: 01/28/2002 BARCO NV, CORONIS 3MP MEDICAL FLAT PANEL DISPLAY SYSTEM™ And 510(k) Number: K032638 Decision Date: 09/11/2003 Planar DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™.
<u>21 CFR 807.92(a)(4)</u> <u>Device Description:</u>	The Planar DOME EX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models E4c Color™ is a flat panel hi-resolution LCD monitor systems for displaying medical images. The system consists of a LCD monitor and a high-resolution graphic control board that connects to a PACS workstation for image display. The controller board is installed into the PACS workstation computer or other computer system used to display PACS medical images. Cxtra is user-friendly software that purpose is to optimize the display for DICOM-compliant viewing.
<u>21 CFR 807.92(a)(5)</u> <u>Intended Use:</u>	The Planar DOME DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model E4c™ is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners. This device must not be used in primary image diagnosis in mammography.

21 CFR 807.92(a)(6)

Substantial Equivalence:

The Planar DOME EX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models E4c Color™ is substantially equivalent to the BARCO NV, CORONIS 3MP MEDICAL FLAT PANEL DISPLAY SYSTEM™ (K013922) and the Planar DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™ (K032638) in that:

- The subsection of the system are similar in that they each consist of:
 - Display Monitor
 - Graphic controller card installed in a PACS or PC.
 - Software
- Intended use is same
- Performance attributes are similar
- Follow DICOM PS3.14 "Grayscale Standard Display Function"

21 CFR 807.92(b)

Conclusions and Statements:

This 510(k) Pre-Market Notification for the Planar DOME EX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models E4c Color™ contain adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The Planar DOME EX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models E4c Color™ has been tested to various Standards and was validated for its intended use.

The Planar DOME EX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models E4c Color™ will be manufactured by in accordance with voluntary and safety standards

This submission contains the results of a hazard analysis and the potential hazards have been classified as Minor

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2006

Planar Systems, Inc.
% Ms. Melissa J. DeGuia
Project Engineer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMS WA 98607

Re: K060136
Trade/Device Name: DOME EX™ Digital Flat-Panel
Display System™, Models E4c™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 18, 2006
Received: January 19, 2006

Dear Ms. DeGuia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 060136

Device Name:

DOME EX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models E4c™ .

Indications for Use:

The Planar DOME DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model E4c™ is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.

This device must not be used in primary image diagnosis in mammography.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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